

## ***Remarks***

### ***35 USC §112(1)***

Claims 2 and 3 stand rejected for lack of support in the specification under §112(1). The amendment to the specification adds the proper support. The original support for the claim amendment is found in the original application at page 13, lines 14-18 (original claims 2 and 3). See MPEP 608.01(o). Claims 7 and 8 stand rejected under §112(1) for lack of support. The support for these claims, as amended, is found at page 5, lines 5-7, which states “polyethylene glycol is a preferred water soluble additive that is added at a concentration of 4 to 30 wt. %, preferably at 4 to 20 wt. % and more preferably at 6 to 16 wt. %.” The amendments to claims 7 and 8 simply correct the typographical error, and have the effect of broadening the claims.

### ***35 USC §112(2)***

Claims 2 and 3 modify the first limitation of claim 1 which recites “an aqueous polyvinyl alcohol solution.” This is the material having the recited concentration ranges of claims 2 and 3. This aqueous polyvinyl alcohol solution in claims 2 and 3 has concentrations expressly recited to be exclusive of *both* the additive and the biologically active material. Referring to claim 1 from which claims 2 and 3 depend, the additive and biologically active material are clearly separate limitations, reflecting separate materials added as recited to the original material of the first limitation of claim 1, which is the “aqueous polyvinyl alcohol solution” recited in claims 2 and 3. This amendment clarifies without narrowing.

Claim 7 and 8 stand rejected under §112(2). The amendment makes clear that the concentrations refer to polyethylene glycol solution. The phrase thereafter “exclusive of the additive” has been eliminated since the recited ranges of claim 7 and 8 do modify the “polyethylene glycol solution” itself, which is the additive.

Claims 13, 14 and 15 stand rejected under 35 USC §112(2). The “gel substance form” recited in those claims is supported in the original specification at page line 7, lines 4-12, which describes the form or shape in which the gel substance is processed according to the invention. In addition to this support, the specification has been amended to add the dimensions as seen in the additional material amended in the specification, the support for which appears in the original application at page 14, lines 21-30 (original claims 13-15). See

MPEP 608.01(o). The gel substance form recitation of claims 13-14 is further supported in the original specification at page 8, lines 12-13.

According, the “gel substance form” of claims 13, 14 and 15 has a specific dimension recited in each of the questioned claims, and additionally has ample support in the original specification.

Finally, the claims have been amended to state “wherein said process yields a gel substance form having...”. This amendment clarifies grammatically the claims in response to the rejection, without narrowing the scope of the claims.

### ***35 USC §103***

Claims 1-19 and 21-24 stand rejected under 35 USC §103(a) as unpatentable over Charmot et al. (U.S. 4,737,533). The same claims are separately rejected under §103 as unpatentable over Venkatraman et al. (U.S. 6,039,977). As discussed in an examiner interview summarized below, the mere recitation of adding polyvinyl glycol and polyvinyl alcohol in these references does not cause the phase separation as recited in the pending claims. The Affidavit of the inventor, Dr. Klaus Dieter Vorlop, filed herewith and incorporated by reference establishes this fact on the record.

Claim 1 has been amended to expressly recite the always inherent property that the process steps are sequential. This amendment does not narrow, since a substantive review of the process steps themselves indicates they are sequential as originally claimed. In any case, neither this inherent property of the original claims nor the expressly recited sequential property of the currently pending claim is suggested, motivated or enabled by either of the recited references cited in the Office Action, or any combination thereof. Accordingly, the claims currently pending should be allowed.

### ***Interview Summary***

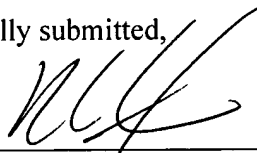
Applicant thanks the Examiner for a useful discussion of the elements of the materials recited in the Venkatramen and Charmot references as compared to the limitations of the pending method claims during the interview of July 28, 2004. It was agreed that the file history would benefit from a §132 Affidavit establishing that the mere addition of polyvinyl glycol to PVA does not cause a phase separation as recited in the pending claims and from a

claim amendment clarifying that the recited process steps are sequential. The amendment does not narrow.

*Conclusion*

The grounds for rejection having been overcome or rendered moot, applicant requests promote and favorable consideration of the pending claims.

Respectfully submitted,



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